

**REMARKS**

To the extent that it is not necessary to address particular items within the Office Action in order to provide a complete response, such as rejections of dependent claims, Applicants' choice not to discuss such items is not, and cannot be interpreted as, acquiescence by the Applicants to such items, nor can it be construed to limit the scope of any claims that may eventually issue in this patent application or any patent application claiming priority to this one.

**35 U.S.C. §102**

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

**Claims 1-10**

The rejection of claims 1-10 is respectfully traversed.

Claim 1 claims "[a]n apparatus for creating an opening in a tissue vessel and introducing an object into the vessel through the opening, the apparatus comprising: a hollow member; a piercing element movable relative to said hollow member to remove a tissue plug from the vessel and thereby create an opening therein; and an introducer located substantially around at least part of said hollow member, wherein said piercing element and said hollow member are movable relative to said introducer to allow introduction of the object into the opening in the vessel through said introducer."

In contrast, Blake does not expressly or inherently describe each and every element of claim 1. First, the Office Action alleges that the claimed introducer corresponds to reference

number 1 in Figures 2, 3 and 8-11. (Office Action, page 2). However, the item having reference number 1 is the vascular punch 1 in its entirety. (Blake; *e.g.*, col. 3, lines 1-25). Indeed, the punch 1 expressly “comprises a blade drum 6 and a punch mandrel 7.” (Blake; col. 3, lines 20-22). Thus, the punch 1 is not a separate element from the blade drum 6 and the punch mandrel 7, as the introducer is required to be; rather, the punch 1 includes the blade drum 6 and punch mandrel 7.

Second, Blake discloses nothing about a workpiece object, much less motion of a piercing element and hollow member relative to the introducer to allow introduction of that workpiece object into an opening in the vessel. The only object in Blake that is introduced into the vessel is the circular disc 56 and the conical portion 57 (if present). (Blake; col. 5, line 34 through col. 2, line 6). The Office Action is silent as to the workpiece object, implicitly agreeing that Blake does not disclose the manipulation of such a workpiece object with the vascular punch 1 disclosed therein.

Third, at no time in the operation of the device of Blake is there space to move a workpiece object through the front opening 32 of the housing 10. The mandrel 7 is positioned within the lumen 65 of the blade drum 6, and is then fixed relative to the housing by a pin 9 such that the mandrel 7 is “immobilized”. (Blake; col. 5, lines 1-5, 13-16). As a result, the mandrel 7 blocks the lumen 65 of the blade drum 6. In turn, the mandrel 7 and the blade drum 6 “extend distally outside of the housing 10 through the front opening 32 therein.” (Blake; col. 3, lines 22-25). In this way, the mandrel 7 and the blade drum 6 block the opening 32 in the distal end of the housing. Further, nowhere does Blake describe any motion of the mandrel 7 and/or blade drum 6 in any direction other than linearly in the proximal and distal directions, such that neither the mandrel 7 nor blade drum 6 can move out of the way to allow passage of a workpiece object. Consequently, the blade drum 6 and mandrel 7 are not

movable relative to the housing 10 or anything else to allow introduction of a workpiece into the opening in the vessel through the housing 10 or any other part of the tool 1 of Blake.

Fourth, the rejection of claim 1 appears to be premised at least partially upon the alleged disclosure in Blake of a "tissue trap member." (Office Action, page 2). However, claim 1 does not claim a tissue trap member.

Thus, Blake does not expressly or inherently describe each and every element of claim 1, and claim 1 is believed to be in condition for allowance. Claims 2-10 depend from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

#### Claims 11-15

The rejection of claims 11-15 is respectfully traversed.

Claim 11 claims "[a] system for performing anastomosis to a tissue vessel; the apparatus comprising: a cutter; an element movable relative to said cutter to remove a tissue plug from the vessel and thereby create an opening therein; an anastomosis device; and an introducer having an axis substantially along which said anastomosis device is introduceable into the opening, wherein said element and said cutter are movable away from said axis to allow motion of said anastomosis device substantially along said axis." (emphasis added).

In contrast, Blake does not expressly or inherently describe the claimed anastomosis device. The device of Blake is simply a vascular punch. Nowhere in the Blake reference is the claimed anastomosis device described. Indeed, Blake fails to describe connecting tissue vessels at all, much less an anastomosis device or any other apparatus or method for making such a connection. For this reason alone, claim 11 is allowable over Blake.

Further, Blake does not disclose an element and a cutter movable away from the axis of an introducer. (emphasis added). The Office Action implicitly admits as much, because it does not address this limitation of claim 11. The mandrel 7 of Blake only moves linearly

along the longitudinal centerline of the blade drum 6. (e.g., col. 5, line 46 through col. 6, line 6; Figures 2-3). Indeed, the inner diameter of the blade drum 6 and the outer diameter of the mandrel 7 are substantially the same, such that the mandrel 7 cannot be moved away from the longitudinal centerline of the blade drum 6 as required by claim 11. (e.g., Figures 2-3). Thus, Blake does not disclose the claimed "introducer having an axis...wherein said element and said cutter are movable away from said axis."

Thus, Blake does not expressly or inherently describe each and every element of claim 11, and claim 11 is believed to be in condition for allowance. Claims 12-15 depend from claim 11, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

#### Claims 16-32

The rejection of claims 16-32 is respectfully traversed.

Claim 16 claims "[a] tissue cutting system for creating an opening in a tissue vessel, comprising: a cutter; a piercing element movable relative to said cutter to remove a tissue plug from the vessel, said piercing element defining a tissue receiving space proximal to its distal end; and a member configured to receive said piercing element, said member having an aperture defined in a side thereof through which said piercing element is at least partially removable." (emphasis added).

In contrast, Blake fails to disclose an aperture defined in the side of any structure through which the piercing element is at least partially removable. The Office Action implicitly admits as much, because it does not address this limitation of claim 16. Turning to Blake, if the housing 10 is considered analogous to the introducer, which is it not, the housing 10 includes no opening defined in a side thereof through which the piercing element is at least partially removable. If the blade drum 6 is considered analogous to the introducer, which it is

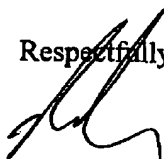
not, the blade drum 6 includes no opening defined in a side thereof through which the piercing element is at least partially removable.

Thus, Blake does not expressly or inherently describe each and every element of claim 16, and Applicants believe claim 16 is in condition for allowance. Claims 17-32 depend from claim 16, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

**REQUEST FOR ALLOWANCE**

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



Brian A. Schar  
Attorney for Cardica, Inc.  
Reg. No. 45,076  
Tel. No. (650) 331-7162